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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/757,775
Filing Date: January 14, 2004
Appellant(s): HO ET AL.

Rodney J. Ho et al.
For Appellants

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/14/2010 appealing from the Office action mailed 11/9/2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-3, 5-9 and 10-17 are pending, claims 10-14 are withdrawn from consideration. Claims 1-3, 5-9 and 15-17 have been rejected.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

U.S. 6,110,491	Kirpotin	10-1996
U.S. 5,258,499	Konigsberg	11-1993
U.S. 5,773,027	Bergeron	6-1998

Thibodeau (Molecular Engineering, 1991, 275-293)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5, 7-9, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirpotin (U.S. 6,110,491, effective filing date, Oct 22 1996).

Kirpotin teaches a liposome composition containing an encapsulated compound and a method of producing the composition. Kirpotin teach exemplary vesicle-forming lipids include the phospholipids, such as phosphatidylcholine, phosphatidic acid, phosphatidylethanolamine, phosphatidylinositol and other suitable lipids include glycolipids, and sterols such as cholesterol (col. 9, 25-28). The reference further teach suitable compounds in the liposome complex preparation include low water solubility compounds preferably in the pH range of 3-9 such as HIV protease inhibitors including indinavir, ritonavair etc. (col. 7, lines 54-56, col. 8, lines 32-33). The reference also teach liposomes composed of the lipids egg phosphatidycholine (PC), cholesterol (CHOL) and teach lipid to drug ratio of 1μm to 200 nm (example 1) which is 5:1. The references teaches that bulk phase pH of the suspension can be within the range pH 6-8 suitable for parenteral use (col. 8, lines 39-40). Kirpotin teaches that liposomes can be prepared in the desired size range, typically between 0.03-1 micron, preferably between 0.03 to 0.5 microns and further teaches that homogenization methods are also useful for down-sizing liposomes to sizes of 100 nm or less (col. 10, lines 1-12).

It would have been obvious to one of ordinary skill in the art to formulate a lipid drug complex because of the teachings of Kirpotin. The reference teaches a liposome composition containing an encapsulated compound and a method of producing the

composition. One of ordinary skill in the art would have been motivated to formulate a lipid-drug complex because of expectation of success as Kirpotin teaches lipid drug complexes with the lipids including phosphatidylcholine. The references do not explicitly teach that the drug substantially dissociates from the lipid-drug complex within a pH range of 5.0-5.5. Kirpotin teach the same components of the lipid-drug complex, the drug indinavir can be entrapped in a liposome as claimed in the instant application. The dissociation of the drug from the complex at the claimed pH range is the property of the lipid-drug complex. Regarding the claimed dissociation properties, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. In the absence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). It would have been obvious to one of ordinary skill in the art at the time of the invention to formulate a lipid-drug complex of 50-80 nm in diameter (as claimed in claim 17) because of the teachings of Kirpotin et al. Kirpotin teach that the liposomes can be prepared in the size range of 100 nm or less. Size is a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of

ordinary skill to determine the optimal size of the vesicles in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kirpotin (U.S. 6,110,491) as applied to claims 1-5, 7-9, 15-17 above and in view of Thibodeau (Molecular Engineering, 1991, 275-293) and Konigsberg et al. (U.S. 5,258,499).

Kirpotin's teachings discussed as above.

Kirpotin does not teach the liposome to be unilamellar.

Thibodeau teach the role of liposomes in antigen delivery, preparation of liposomes and further teach that the most commonly used lipids are phospholipids, major structural components of biological membranes and the most common phospholipid is phosphatidyl choline (PC) (p 276, para 4). The reference also teach that the liposomes may differ with respect to dimension (from 25 nm to several microns in diameter) and structure (monolamellar or multilamellar). The reference also teaches the preparation of unilamellar liposome (p 281, preparation of immunosomes).

Konigsberg et al. teach delivery vehicle formulations comprising active agents encapsulated within liposomal vehicles (see Abstract). The reference teach that unilamellar liposomal liposomes have been shown to be useful in targeting solid tumors and to have greater circulation times than other vehicles (col. 15, lines 29-32).

It would have been obvious to one of ordinary skill in the art at the time of the invention to make a lipid drug complex where the liposome is unilamellar because of the teachings of Thibodeau and Konigsberg et al. Thibodeau teach the preparation of unilamellar liposomes in antigen delivery and Konigsberg et al. teach that unilamellar liposomal liposomes have been shown to be useful in targeting solid tumors and to have greater circulation times than other vehicles. One of ordinary skill in the art would have been motivated in expectation of success in preparation of unilamellar liposomes from Thibodeau's teachings and to target solid tumors and for greater circulation times than other vehicles by formulating unilamellar liposomes as stated by Konigsberg.

Claims 1-3, 5-9, 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. (U.S. 5,773,027) in view of Kirpotin (U.S. 6,110,491, effective filing date, Oct 22 1996).

Bergeron et al. teaches formulation of liposomes for the treatment of a viral disease which comprises: 1) a lipid component comprising a mixture of diacylphosphatidylcholine and diacylphosphatidyl glycerol and ii) a therapeutic amount of an entrapped drug such as saquinavir effective against said viral disease (see Abstract, claims 1 and 5-10). The reference teaches the preparation of unilamellar liposomes (col. 4, line 53). The reference teaches the intravenous administration of liposomes to rats (Table 3). The reference teaches the same drug (saquinavir) as claimed in claim 9 of the instant application. Hence this meets the limitation of at least one drug molecule having low aqueous solubility within a neutral pH range.

The reference does not teach indinavir (elected species) as the drug and phosphatidyl choline (elected species) as the lipid in the lipid-drug complex.

Kirpotin's teachings discussed as above. Kirpotin teach the same components of the lipid-drug complex, the drug indinavir can be entrapped in a liposome as claimed in the instant application. The reference also teaches that the lipid-drug complex can be parenterally administered and subcutaneous administration is a type of parenteral administration.

It would have been obvious to one of ordinary skill in the art to formulate a lipid drug complex comprising indinavir as the drug and phosphatidylcholine as the lipid in the lipid-drug complex because of the teachings of Kirpotin. The reference teaches a formulation comprising the lipid and a drug and further teaches phosphatidylcholine as one of the exemplary lipid. One of ordinary skill in the art at the time of invention would have been motivated to formulate indinavir as the drug in the lipid-drug complex because Kirpotin teaches the equivalence of indinavir and saquinavir. Also one of ordinary skill in the art at the time of invention would have been motivated to achieve similar or better therapeutic benefits in using one anti-HIV drug for another in the formulation. One of ordinary skill in the art would have been motivated to formulate a lipid-drug complex using phosphatidylcholine because of expectation of success as Kirpotin teaches lipid drug complexes with the lipids including phosphatidylcholine. The references do not explicitly teach that the drug substantially dissociates from the lipid-drug complex within a pH range of 5.0-5.5. Kirpotin teach the same components of the lipid-drug complex, the drug indinavir can be entrapped in a liposome as claimed in the

instant application. The dissociation of the drug from the complex at the claimed pH range is the property of the lipid-drug complex. Regarding the claimed dissociation properties, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. In the absence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

(10) Response to Argument

1. The rejection of claims 1-3, 5, 7-9, and 15-17 under 35 U.S.C. §103(a) as being unpatentable over Kirpotin, U.S. Patent No. 6,110,491 ("Kirpotin").

Applicants argue that (1) Kirpotin does not teach that the drug encapsulated in Kirpotin's drug-encapsulating liposomes "substantially dissociates from the lipid-drug complex within a pH range of 5.0-5.5", (2) Kirpotin does not teach the currently claimed invention and (3) the statement that "The dissociation of the drug from the complex at the claimed pH range is the property of the lipid- drug complex," is conclusionary with no support.

In response, Kirpotin teaches a liposome composition containing an encapsulated compound, the lipids selected from exemplary vesicle-forming lipids such as phosphatidylcholine, phosphatidylethanolamine, phosphatidic acid,

phosphatidylinositol, sphingomyelin, glycolipids, cholesterol etc (col. 9, lines 25-34), the compounds or drugs selected from ceflalosporines (anti-bacterial), acyclovir, gancyclovir, indinavir, saquinavir, ritonavir (anti-viral, anti-HIV drugs), tamoxifen (anti-cancer, specific for breast cancer treatment), non-steroid anti-inflammatory agents: ibuprofen etc. (col. 7, lines 64-67, col. 8, lines 20-24). It is known that liposomes are lipid vesicles used to convey vaccines, drugs, enzymes, or other substances to target cells or organs. Applicants claim a lipid-drug complex comprising at least one lipid and at least one drug molecule having low aqueous solubility within a neutral pH range and wherein the at least one drug molecule substantially disassociates from the lipid-drug complex within a pH range of about 5.0-5.5. The claim is towards a composition comprising one or more lipids and one or more drug molecules and one or more drug molecule substantially disassociates at pH 5-5.5. Furthermore Applicants claim liposome as a lipid-drug complex (claim 5), claim the lipids that include phospholipids, sphingolipids, spingomyelin, glycolipids, cholesterol etc, claim the drugs that include anti-viral, anti-HIV, anti-bacterial, anti-cancer, drug that inhibits the growth of breast cancer, and further claim specific drugs that includes indinavir, saquinavir, nelfinavir etc (claims 7-15). Kirpotin teaches a liposome (a lipid-drug complex) comprising the "claimed" lipids that includes phospholipids, sphingomyelin, glycolipids cholesterol etc and the "claimed" drugs including indinavir, saquinavir, acyclovir (anti-viral), tamoxifen (anti-cancer) etc. Kirpotin teaches the same components of the lipid drug complex as claimed by the Applicants. The dissociation of the drug from the complex at the claimed pH range is the property of the lipid- drug complex," is not conclusionary as Applicants

argue because, Kirpotin's lipid-drug complexes comprise the same lipids and drugs as claimed by the Applicants as shown above and accordingly, the dissociation property of the lipid-drug complexes of Kirpotin would be expected to be substantially similar as claimed by the Applicants, including that "at least one drug molecule substantially disassociates from the lipid-drug complex within a pH range of about 5.0-5.5". The low aqueous solubility is a property of the drug and the dissociation of the drug at a certain pH is the property of the drug and the drug complex. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. Applicants have not shown any technical substantial evidence in the form of experimental data that prior art lipid-drug complex which comprises the same components, the "claimed lipid" (e.g. phopholipids like phosphatidylcholine, cholesterol, glycolipids etc) and the "claimed drug" (such as indinavir, saquinavir etc) is not the same as the composition claimed by the Applicants. As Kirpotin teaches a lipid-drug complex, liposome with the claimed elements, a lipid (e.g. phosphatidyl choline) and a drug with low aqueous solubility in the neutral pH range (e.g indinavir) it would have been obvious to a person of ordinary skill in the art at the time of the invention that the dissociation properties of Kirpotin's lipid-drug complexes would be expected to be substantially similar to the claimed limitation of "wherein the at least one drug molecule substantially dissociates from the lipid-drug complex within a pH 5.0-5.5 range.

Applicants' argue that "one of ordinary skill in chemistry or biochemistry would necessarily conclude that the rigid-lipid- bilayer liposomes created by Kirpotin's method are very different from the lipid-drug complex claimed in claim 1". Applicants' further argue that "Kirpotin beginning on line 34 of column 8, the internal pH of the liposomes is preferably at or near the minimum-solubility pH of the precipitated compound, or at a lower pH of 4 to 5.5 or an upper pH of 8.5 to 10. Thus, as clearly stated by Kirpotin, an encapsulated drug such as indinavir, appreciably soluble only at very low pH, is precipitated and thus unavailable for release or dissociation from the liposomes at the very pH range of 5.0 to 5.5 that the currently claimed lipid-drug complex allows the drug to dissociate. In other words, Kirpotin explicitly teaches that the precipitated drug within Kirpotin's drug encapsulating liposomes cannot dissociate from the liposomes in the pH range of about pH 5.0 to about pH 5.5 at which the drug dissociates from the currently claimed lipid-drug complex. The currently claimed lipid-drug complex is prepared by a very different method than Kirpotin's drug-encapsulating liposomes".

In response to Applicants' argument that Kirpotin's method of preparing lipid-drug complexes is very different than the currently claimed lipid-drug complex, the claims of the instant invention are towards a composition comprising at least one lipid molecule, at least one drug molecule having low aqueous solubility and the method of preparation is irrelevant here because given the broadest reasonable interpretation of the claim and not importing the claim limitations from the specification to the claim, the claims of the instant invention are towards a composition comprising at least one lipid molecule, at least one drug molecule having low aqueous solubility and the claims are not toward a

process or method of making comprising different steps. There are no limitations in the claims that the composition is prepared in a specific technique or consists of specific components with any specific amounts. The claims are towards a composition with a comprising language and are very broad with respect to the active ingredients in the claims including the lipids, the drugs and their amounts. A lipid-drug complex of Kirpotin comprising the "claimed" lipid (e.g phospholipids) and a drug molecule (e.g indinavir, a drug with low aqueous solubility) teaches the composition claimed by the Applicants. As stated above, the limitation "wherein the at least one drug molecule substantially dissociates from the lipid-drug complex within a pH 5.0-5.5 range" is the property of the drug complex and the dissociation properties of Kirpotin's lipid-drug complexes would be expected to be substantially similar to the properties of the claimed composition. Applicants have not provided any experimental data or any technical substantial evidence that the prior art Kirpotin's drug complexes prepared by a different method is not the same as the composition claimed by the Applicants.

Applicants' argue that "as clearly stated by Kirpotin, an encapsulated drug such as indinavir, appreciably soluble only at very low pH, is precipitated and thus unavailable for release or dissociation from the liposomes at the very pH range of 5.0 to 5.5 that the currently claimed lipid-drug complex allows the drug to dissociate. Kirpotin teaches encapsulation of the drugs within the liposome by pH precipitation method. The reference in col. 8, lines 34-37 teaches that the internal pH of the liposomes in the composition is preferably at or near the minimum solubility pH of the precipitated compound, or at a lower pH of 4 to 5.5 or an upper pH of 8.5-10. Accordingly, the drug

or the compound can be precipitated at 3 different pH conditions. Hence a compound such as indinavir with a low aqueous solubility or appreciably soluble only at very low pH can be precipitated at or near the minimum solubility pH of indinavir or at an upper pH of 8.5-10. If precipitated at those pH conditions the drug can dissociate at a pH range of 5.0-5.5. In the example by Kirpotin (Example 1), liposome comprises egg phosphatidylcholine, cholesterol (claimed lipids) and drug (doxorubicin, an anti-cancer agent, a claimed drug) in the ratio of 5:1 (example 1, doxorubicin 200 nmol/umol of liposomal phospholipid) and teaches the NaCl HEPES solution in the preparation. In general, the buffer range for Hepes buffer has a pH of 6.8-8.2. Accordingly, the liposomes prepared with doxorubicin for example has been precipitated and encapsulated at a pH range other than 5 -5.5 and is available for release at a pH of 5-5.5. Similarly drug indinavir as claimed by the Applicants can be precipitated and encapsulated at a pH other than 5-5.5 and will be available for release at a pH of 5-5.5. Kirpotin's teachings do not state or indicate that the drug has to be precipitated at a pH of 5-5.5 as argued by the Applicants. In fact, Kirpotin shows a comparison data of precipitating doxorubicin at pH 7. 3 and pH 5.2 based on the addition of ammonium sulfate or polyacrylate in the composition (example 7). Moreover, Applicants' arguments are with respect to one drug indinavir. However the scope of the composition claims are very broad with respect to the drugs as it can include at least one drug (e.g anti-viral, anti-HIV, immunomodulatory, anti-cancer, anti-fungal, anti-bacterial etc) and at least one lipid. According to Kirpotin, compounds including drugs with lower aqueous solubility at a neutral pH range can be either encapsulated at or near the minimum

solubility pH or at an upper pH of 8.5-10 and the drug can be dissociated or released at a desired pH.

Applicants' argue that Kirpotin's drug encapsulating liposomes are considered to be stable in the pH ranges of 5.0-5.5 and even in the presence of ionophores, do not release their contents (Kirpotin's abstract) and hence is different from the claimed invention.

In response, as stated above, Kirpotin explicitly teaches in col. 8, lines 34-37 that the internal pH of the liposomes in the composition is preferably at or near the minimum solubility pH of the precipitated compound, or at a lower pH of 4 to 5.5 or an upper pH of 8.5-10. Hence the drug can be precipitated at pH conditions at or near the minimum solubility of the compound and not necessarily at a pH of 5-5.5. According to the teachings of Kirpotin, a liposome with an encapsulated drug can be stable at various pH ranges, including the pH range of 5-5.5.

(2) *The rejection of claim 6 under 35 U.S.C. §103(a) as being unpatentable over Kirpotin in view of Thibodeau, Molecular Engineering, 1991, pp 275-293 ("Thibodeau") and Konigsberg et al., U.S. Patent No. 5,258,499 ("Konigsberg").*

Applicants argue that claim 6 depends primarily on Kirpotin and Kirpotin does not teach, mention, or suggest that for which it is cited and Thibodeau and Konigsberg differ significantly than those used to prepare the lipid-drug complex of the current invention.

In response, as stated above, Kirpotin teaches a lipid-drug complex, liposome with the claimed elements, a lipid (e.g. phosphatidyl choline) and a drug with low aqueous solubility in the neutral pH range (e.g indinavir) and that the dissociated

property of Kirpotin's lipid-drug complexes would be expected to be substantially similar to the claimed limitation of "wherein the at least one drug molecule substantially dissociates from the lipid-drug complex within a pH 5.0-5.5 range. Hence the claimed invention would have been obvious over the prior art Kirpotin.

Thibodeau and Konisberg has been cited to show that unilamellar liposomes are known in the art and the preparation of such unilamellar liposomes comprising a drug and a lipid are within the capability of the ordinary artisan. Konisberg in addition provides motivation to prepare unilamellar liposomes as they have been shown to be useful in targeting solid tumors and to have greater circulation times than other vehicles. Accordingly, the claimed invention would have been obvious over the combined teachings of Kirpotin, Thibodeau and Konisberg.

(3) The rejection of claims 1-3, 5-9, 15-17 under 35 U.S.C. §103(a) as being unpatentable over Bergeron et al., U.S. Patent No. 5,773,027 ("Bergeron") in view of Kirpotin.

Applicants argue that Bergeron or Kirpotin does not teach, mention, or even remotely suggest the currently claimed lipid-drug complex that releases the drug in a pH range of about pH 5.0 to about pH 5.5.

In response, Bergeron teaches treatment of viral diseases comprising administering antiviral agents encapsulated in liposomes. Liposomes are lipid vesicles used to convey vaccines, drugs, enzymes, or other substances to target cells or organs. The reference states that the preparation of liposomes can be done by a variety of techniques such as those described in the literature and further states that preparation

of unilamellar and multilamellar liposomes are known in the art (See col. 4, Preparation of liposomes). The reference teaches a lipid-drug complex comprising diacylphosphatidyl glycerol, cholesterol and diacylphosphatidylcholine (claimed lipids) and a therapeutic amount of an entrapped drug such as saquinavir (claimed drug) effective against said viral disease. Bergeron teaches preparation and delivery of liposome, a lipid-drug complex comprising the "claimed" lipid (e.g phospholipid) and the "claimed" drug (saquinavir, an anti-viral drug). The drug teaches the delivery of the drug in vivo by administration to rats. In summary, Bergeron teaches the lipid-drug complexes comprising the same components, with a claimed lipid and with a claimed drug the composition, As Bergeron teaches the lipid-drug complexes comprising the claimed lipids and drugs, the dissociation property of Bergeron's lipid-drug complexes would be expected to be substantially similar to the claimed limitation of "wherein the at least one drug molecule substantially dissociates from the lipid-drug complex within a pH 5.0-5.5 range. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same functional characteristics of the claimed product. Applicants have not shown any technical substantial evidence in the form of experimental data that prior art lipid-drug complex which comprises the same components, the "claimed lipid" (e.g. phopholipids) and the "claimed drug" (such as saquinavir) is not the same as the composition claimed by the Applicants. As Bergeron teaches a lipid-drug complex, liposome with the claimed elements, a lipid (e.g. phospholipid) and a drug with low aqueous solubility in the neutral pH range (e.g

saquinavir) it would have been obvious to a person of ordinary skill in the art at the time of the invention that the dissociation property of the lipid-drug complexes by Bergeron would be expected to be substantially similar to the claimed limitation of "wherein the at least one drug molecule substantially dissociates from the lipid-drug complex within a pH 5.0-5.5 range. Accordingly, the claims of the instant application would have been obvious over the prior art teachings of Bergeron. Kirpotin has been cited as a secondary reference to teach the equivalence of indinavir (elected species) and saquinavir (anti-HIV drugs).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

July 28 2010

/SREENI PADMANABHAN/

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